UNITED STATES PATENT AND TRADEMARK OFFICE



Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

MAR 2 3 2007

Mary-Ellen M. Devlin Patent Department Boehringer Ingelheim Corp. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877

In re Patent Term Extension Application of

U.S. Patent No. 5,610,163

Issue Date: March 11, 1997 : Decision on Petition to

U.S. Application No. 08/405,111 : Stay Grant of Certificate in Patent

PTE Filing Date: March 15, 2004 : Term Extension Application

For: Inhibitors of Thrombin

The above-identified application has been forwarded to the Office of Patent Legal Administration in the United States Patent and Trademark Office (the "Office") for consideration of a petition titled "Petition to Stay Proceedings re: Patent Term Extension Application for U.S. Patent No. 5,610,163 under 37 C.F.R. §§ 1.182 and/or 1.183," which was filed on February 22, 2007.

The petition is granted for a period of 6 months from the mailing date of this decision.

Background and Analysis

On April 3, 2006, Petitioner informed the Office that a reissue application for U.S. Patent No. 5,610,163 had been filed on October 18, 2005, and had been assigned Reissue Application No. 11/254,213.

On January 23, 2007, the Office issued a Notice of Final Determination on Petitioner's application for patent term extension of U.S. Patent No. 5,610,163 (PTE application) covering Petitioner's NDA-approved drug product Spiriva® Handihaler® (tiotropium bromide monohydrate) indicating that a certificate of extension would be issued to the patent holder, Boehringer Ingelheim Corporation, for a period of 1,421 days.

Petitioner now petitions for a stay of the processing of its PTE application, specifically, a stay of the issuance of the certificate of extension so that prosecution of the reissue application can be concluded and the patent reissued, therefore permitting the certificate of extension to be granted on the reissued patent.

Although Petitioner has petitioned under 37 C.F.R. § 1.183, Petitioner has not recited a specific rule to waive. Since the only rule which could be waived regarding issuance of a certificate of extension is 37 C.F.R. § 1.780 and applicants do not wish to waive that rule, merely stay action on that rule, the petition under 37 C.F.R. § 1.183 is moot. The Office treats the present petition as falling under 37

C.F.R. § 1.182, which addresses all situations not specifically provided for in other regulations. Further, the Office analogizes the request made by Petitioner to requests for staying action in patent applications and for deferring issuance of a patent filed under 37 C.F.R. § 1.103 and 37 C.F.R. § 1.314 respectively. The standard for granting requests under both 37 C.F.R. § 1.103 and 37 C.F.R. § 1.314 is good and sufficient cause. Accordingly, the Office shall apply that same good and sufficient cause standard to the present petition under 37 C.F.R. § 1.182.

Since a stay in the proceedings of the patent term extension application in order to conclude the reissuance of the patent appears to constitute good and sufficient cause, a stay is granted for a time period of 6 months from the mailing date of this decision.

Conclusion

The petition under 37 C.F.R. §§ 1.182 and 1.183 is granted for a period of 6 months from the mailing date of this decision.

The rules and statutory provisions governing the operations of the U.S. Patent and Trademark Office require payment of a fee on filing each petition. See 37 C.F.R. § 1.17(f). The required petition fees have been received for the present petition.

Telephone inquiries with regard to this communication should be directed to Mary C. Till at (571) 272-7755.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy